FILED
JAN 28 2002
Phil Lombardi, Clerk
U.S. DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF OKLAHOMA

DAWANNA ROBERTSON and STEPHEN ROBERTSON, individually and as parents and next friend of SYDNEE ROBERTSON, a minor child, JEFFREY TEEL and PAIGE TEEL, JULIE HORN, individually, and as administratrix of the estate of DON E. HORN, DEBORAH WYNN, MARK GAFFNEY, BEVERLY ANN HARRIS, and LESTER HARRIS, PATRICIA ANNE YOUNG, SHARON LEA MORGAN, and RONALD EUWELL WATKINS, individually and as the co-trustee of the ELLA OLGIA WATKINS REVOCABLE TRUST, SHIRLEY ROGERS, and BOB ROGERS, PATRICK ADMIRE, as personal representative of the estate of KATHLEEN C. WEDDLE, deceased, PHYLLIS FRIESNER, as personal representative of the estate of JAMES F. FRIESNER, deceased, and SANDRA GRUBBS, as administratrix of the estate of TERRELL GRUBBS, deceased,

Plaintiffs,

vs.

Case No. 01-CV-60-C

MICHAEL MCGEE, M.D.,DANIEL PLUNKET, M.D. LINDA ANDREWS, R.N., KEVIN DONOVAN, M.D., LARRY EVANS, J.D., GLENN LYTTE, M.D., KATHLEEN RAYMAN, Ph.D, R.N., TERRY MOOREHEAD, R.PH., JULIE WARRECK, M.D., ANTONIO DELEON, JR.,M.D., PAM PRICE HOPKINS, Ph.D., R.N., MICHAEL BOYLE, M.D., STEVE BUCK, EDWARD WORTHAM, JR., Ph.D., HAROLD L. BROOKS, M.D., THOMAS BROUGHAN, M.D., ST. JOHN MEDICAL CENTER, HOAG CANCER CENTER, PATRICK GOMEZ, M.D., CANCER & HEMATOLOGY CENTER, and IMMUNEX CORPORATION.,

Defendants.

ORDER

The Court has before it a series of motions to dismiss plaintiffs' first amended complaint filed by the defendants, except for defendant Daniel Plunket, who filed a motion for summary judgment. Defendants' motions each raise similar grounds for dismissal. The defendants seek dismissal for lack of subject matter jurisdiction under Rule 12(b)(1) F.R.Cv.P., failure to state a claim under Rule 12(b)(6) F.R.Cv.P., and misjoinder of parties under Rule 20 F.R.Cv.P.

The first amended complaint is 188 pages in length, setting forth 122 causes of action, by 18 plaintiffs, against 21 defendants. Plaintiffs seek subject matter jurisdiction under the federal question statute, 28 U.S.C. § 1331. Federal question jurisdiction is purportedly invoked through 42 U.S.C. § 1983 by two sources. First, under the federal constitution by imputing the standards of The Nuremberg Code and the Declaration of Helsinki "to be treated with dignity". Second, through 45 C.F.R. Part 46, asserting a claim for violation of the federal regulations for the protection of persons who participate in clinical research studies. Plaintiffs also seek to invoke supplemental jurisdiction raising state law claims for breach of contract, intentional and negligent infliction of emotional distress, common law fraud/intentional misrepresentation, negligence, assault and battery, and product liability. Plaintiffs seek compensatory and punitive damages.

This action evolves out of a melanoma cancer research study conducted by defendant Dr. Michael McGee at the University of Oklahoma Health Science Center--Tulsa campus. Dr. McGee, the Sponsor and Principal Investigator, had received authorization from the Federal Drug Administration (FDA) to conduct a "human clinical trial" using an investigational melanoma vaccine. The plaintiffs include former participants in the study, their spouses, a minor child, and the personal representatives of deceased participants. The participants suffered from melanoma cancer

and agreed to participate in the study which is the subject of this litigation. The melanoma vaccine was a biological agent prepared by Dr. McGee and his staff using human cancer cells.

Defendant Michael McGee was an Assistant Professor of Medicine, Division of Surgery, at the University of Oklahoma Health Science Center–Tulsa Campus (OUHSC-T). Defendants Daniel Plunket, Linda Andrews, Kevin Donovan, Larry Evans, Jr., Glenn Lytte, Kathleen Rayman, Terry Moorehead, Julie Warreck, Antonio deLeon, Pam Price-Hopkins, Michael Boyle, and Steve Buck were members of the Institutional Review Board at OUHSC-T. Defendant Edward Wortham, Jr.was the Director of the Office of Research at the OUHSC-T. Defendant Harold Brooks was the Dean of the Oklahoma University College of Medicine in Tulsa and was the chief operating officer for the OUHSC-T. Defendant Thomas Broughan was the Chair of the Department of Surgery at OUHSC-T and Dr. McGee's direct supervisor. Defendants St. John's Medical Center, Immunex Corporation and Hogue Cancer Center are private institutions who participated in some manner in the melanoma study.

Defendants Michael McGee, Edward Wortham, Jr., Harold L. Brooks, Thomas Broughan, Michael Boyle, Steven Buck, Antonio deLeon, Jr., Kevin Donovan, Larry Evans and Terry Moorehead, each also allege that plaintiffs' claims are barred by the doctrine of qualified immunity in that they were acting within their capacity as state actors, by virtue of the positions they held with the University of Oklahoma. These defendants, along with defendant Daniel Plunket, also assert that plaintiffs' first amended complaint is barred by the Oklahoma Tort Claims Act.

Additionally, defendants St. John Medical Center, Hoag Cancer Center, and Immunex Corporation also claim that plaintiffs' cause of action under 42 U.S.C. §1983 fails against them in

that they are private entities, rather than state actors, and thus are not subject to claims brought under § 1983.

The essence of plaintiffs' first amended complaint is that because the defendants failed to comply with federal regulations for the protection of human research subjects, and because the defendants failed to promptly notify plaintiffs of this fact, the plaintiffs' involvement in the study was without their consent, and the injection of the non-conforming experimental vaccine into their person was a battery, which caused them severe physical and emotional injury for which they seek monetary relief.

The question before the Court is whether the plaintiffs have properly invoked subject matter jurisdiction under 28 U.S.C. § 1331, which provides a statutory basis for federal jurisdiction over claims "arising under the Constitution, laws or treaties of the United States". Plaintiffs contend their claims arise under 42 U.S.C. § 1983 to redress the deprivation of (1) their federal constitution "right to be treated with dignity"and (2) the federal regulations for the protection of "human research subjects." After review of all the pleadings filed and in consideration of applicable law, the Court finds and concludes that plaintiffs' first amended complaint is subject to dismissal for lack of federal court jurisdiction.

In Blessing v. Freestone, 520 U.S. 329 (1997), the Supreme Court addressed the perimeters of a claim brought under 42 U.S.C. §1983.

> Section 1983 imposes liability on anyone who, under color of state law, deprives a person 'of any right, privileges or immunities secured by the Constitution and laws.' We have held that this provision safeguards certain rights conferred by federal statutes. In order to seek redress through § 1983, however, a plaintiff must assert the violation of a federal *right* not merely a violation of federal *law*.

520 U.S. at 340 (emphasis in text).

Plaintiffs state their constitutional claim as a violation of their privacy right "to be treated with dignity" and their liberty interest to due process. Such vague claims have no support in federal law. The due process clause cannot be interpreted to impose federal rights that are more appropriately state tort claims. The cases cited by plaintiffs primarily involve non-consensual administration of medication or lack of consent to medical experiments. In this instance, the plaintiffs volunteered to be participants in the melanoma vaccine study. At the onset, the plaintiffs' participation in the study was consensual, even though the study was ultimately closed for failure to comply with federal standards. To have a §1983 claim, it is not sufficient to show that a physician exposed a person to an unreasonable risk of harm, ordinary negligence, or medical malpractice. Such allegations do not rise to the level of a constitutional claim or fundamental right guaranteed by the Fourteenth Amendment. See, Daniels v. Gilbreadth, 668 F.2d 477, 486 (10th Cir. 1982).

Although somewhat unclear, apparently, plaintiffs are contending that by defendants conducting the melanoma study in violation of federal regulations for the protection of human subjects, such conduct gives rise to an independent private cause of action by incorporating the Declaration of Helsinki and the Nuremberg Code. Plaintiffs contend that these international laws are the "minimum international standards of conduct governing biomedical research on human subjects into which all the citizens of all nations are subject." This Court agrees with other jurisdictions which have found that there is no private right of action for an alleged violation of international law for the protection of human research subjects under the Declaration of Helsinki and the Nuremberg Code. See. e.g. White v. Paulsen, 997 F.Supp.1380,1383 (E.D.Wash.1998), and Hoover v. West Virginia Department of Health and Human Services, 984 F. Supp. 978 (S.D.W.Vr.1997) aff'd 129 F.3d 1259 (11th Cir. 1997). Moreover, the standard in the United States for conducting research on

human subjects is contained in the Code of Federal Regulations and, thus, there is no need for the courts to resort to international law to impute a standard.

However, the Court finds that there is no private right of action under 21 C.F.R. §§ 210, 211 and 45 C.F.R. Part 46. See, Robinett v. United States, 62 F.3d 1433 (Fed.Cir. 1995)(unpublished). The Supreme Court has held that the Federal Drug and Cosmetic Act (FDCA) does not create or imply a private right of action for individuals injured as a result of a violation of the Act. See, Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804 (1986).

The Supreme Court has stated that a particular federal *law* will not give rise to a federal *right* if Congress foreclosed recourse to §1983 either expressly in §1983, the statute itself, or impliedly, by creating a comprehensive enforcement scheme that is incompatible with individual enforcement under § 1983. See, Blessing v. Freestone, 520 U.S. at 341. Within 21 C.F.R. §§ 210, 211 and 45 C.F.R. § 46, there is a comprehensive enforcement scheme provided to the FDA, accordingly there is no private right of action enforceable under § 1983. "[C]laims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA, especially in light of Congress's intention to repose, in that body, the task of enforcing the FDCA. See, Cottrell, Ltd. v. Biotrol International, Inc., 191 F.3d 1248, 1254 (10th Cir. 1999), *citing with approval* Braintree Labs, Inc. v. Nephro-Tech, Inc., 1997 WL 94237 (D.Kan. Feb.26, 1997)(unpublished). See also, Eon Labs Man., Inc. v. Watson Pharmaceuticals, Inc., 164 F.Supp.2d 350, 361 fn.14 (S.D.N.Y. 2001). Because there is no private right of action under the federal regulations in question, § 1983 cannot be used to create a private right of action which otherwise does not exist. "[O]ne cannot go into court and claim a 'violation of §1983' -- for § 1983 itself does not protect anyone against anything. . . . The act only gives a remedy." Chapman v.

Houston Welfare Rights Org., 441 U.S. § 600, 617 (1978). "Standing alone, § 1983 clearly provides no protection for civil rights since . . . § 1983 does not provide any substantive rights at all."Id. at 618.

Additionally, the defendants who are state actors raise the defense of qualified immunity against plaintiffs' § 1983 claim. In actions brought against state actors performing discretionary functions, the defense of qualified immunity shields them from liability in damages if their conduct does not violate clearly established statutory or constitutional rights which a reasonable person would have known. See, Barney v. Pulsipher, 143 F.3d 1299, 1309 (10th Cir. 1998). "In analyzing qualified immunity claims, we first ask if a plaintiff has asserted the violation of a constitutional right at all, and then assess whether the right was clearly established at the time of defendants' actions." Id. *citing* Gehl Group v. Koby, 63 F.3d 1528, 1533 (10th Cir. 1995). "Where a plaintiff fails to demonstrate that a defendant's conduct violated the law, we need not reach the issue of whether the law was clearly established." Id. As previously stated, there is no federal law which recognizes a constitutional right under 42 U.S.C. § 1983 "to be treated with dignity"for persons who agreed to participate in a medical research project sponsored by a state university.

Similarly, plaintiffs have failed to state a § 1983 claim against the defendants who are private entities because those claims are dependent on the viability of plaintiffs' claim against the state actors. See, e.g., Pino v. Higgs, 75 F.3d 1461, 1465 (10th Cir.1996)("In order to hold a private individual liable under §1983, it must be shown that the private person was jointly engaged with state officials, or that the private individual's conduct is in some other way chargeable to the State.")

Accordingly, the Court finds and concludes that the plaintiffs have failed to establish subject matter jurisdiction in federal court. The Court declines to assume supplemental jurisdiction over plaintiffs' state law claims. Thus, defendants' motions to dismiss are hereby granted.

IT IS THEREFORE THE ORDER OF THE COURT, that plaintiffs' first amended complaint is dismissed for lack of subject matter jurisdiction.

IT IS SO ORDERED this 28th day of January, 2002.

H. DALE COOK
Senior United States District Judge